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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,405	11/30/2004	Wolfgang Demmer	DES: 3568.0099	2828
152 7590 07/03/2007 CHERNOFF, VILHAUER, MCCLUNG & STENZEL 1600 ODS TOWER 601 SW SECOND AVENUE PORTLAND, OR 97204-3157			EXAMINER FERNANDEZ, SUSAN EMILY	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 07/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,405	Applicant(s) DEMMER ET AL.	
	Examiner Susan E. Fernandez	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments filed January 16, 2007, have been received and entered.

Claims 1-15 are pending. Claims 1-10 are withdrawn. Claims 11-15 are examined on the merits to the extent they read on the elected subject matter and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claim 11 has been amended to recite that the at least one protease inhibitor is coupled by a nonionic chemical bond to the membrane body via the functional groups, which is considered to be new matter. The specification as filed does not provide any indication of the type of chemical bonding occurring between the protease inhibitor and the membrane body. Moreover, the specification does not even specify nonionic chemical bonding. Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grano et al. (International Journal of Artificial Organs, 2002, 25(4): 297-305) in view of Burtin et al. (US 6,248,238).

Grano et al. discloses a membrane loaded with antiproteases for reducing the active protease blood concentration (abstract), wherein a protease/antiprotease complex is formed upon contacting the membrane with a solution containing proteases (page 298, first column, first paragraph). An antitrypsin is immobilized via diazotization occurring through tyrosine residues (page 299, first column, first full paragraph and Figure 1). Thus, the protease inhibitor (antitrypsin) is coupled to the membrane body via functional groups, where nonionic chemical

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bonding occurs. Further still, it is noted that trypsin is a serine protease (page 300, second column, second paragraph under "Results").

Grano et al. differs from the claimed invention in that it does not expressly disclose a device having a housing with a fluid inlet and a fluid outlet comprising a plurality of membranes.

Burtin et al. discloses a medical apparatus for the extracorporeal treatment of blood or plasma, comprising a semi-permeable membrane with protease inhibitors (column 4, lines 34-36). The apparatus clearly comprises a housing having a fluid inlet and a fluid outlet (see Figure 5).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used the Grano membranes in a series in a medical apparatus for the extracorporeal treatment of blood. One of ordinary skill in the art would have been motivated to do this since Burtin et al. demonstrates that protease inhibitors on membranes in a housing with a fluid inlet and a fluid outlet is suitable for treatment of blood. Further more, the use of multiple membranes in a series would have ensured thorough reduction of the active protease blood concentration.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grano et al. and Burtin et al. as applied to claim 11 above, and further in view of Bergmann (US 5,168,041).

As discussed above, Grano et al. and Burtin et al. render claim 11 obvious. However, they do not expressly disclose using different protease inhibitors in each of the membranes of the device rendered obvious by Grano et al. and Burtin et al., or that each membrane contains two

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different protease inhibitors, or that the protease inhibitors are any of the compounds (pepstatin and the elected species) recited in instant claim 13.

Bergmann lists various protease inhibitors on Table 1 at column 4, where the table includes pepstatin and the elected species recited in instant claim 13.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used different compounds as the protease inhibitors present in the membranes of the device, where the different compounds may be present in different membranes and/or combined with other protease inhibitors in the same membrane. One of ordinary skill in the art would have been motivated to do this in order to have separated a variety of proteases from a solution, or to have ensured that a specific protease is indeed separated from a solution. It would have been obvious to have used compounds recognized in the art as protease inhibitors, such as those listed in Table 1 at column 4 of Bergmann, in the device, as Nemori et al. does not limit the protease inhibitor included in its thin membranes (column 9, lines 37-39 of English equivalent). Thus, claims 12-14 are also rendered obvious.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed January 16, 2007, have been fully considered but they are not persuasive. Though Bergmann does not expressly disclose p-aminobenzamidine, the previous office action states that it would have been obvious to have used known protease inhibitors. Therefore, p-aminobenzamidine was rendered obvious. It is also respectfully noted that Bergmann was provided solely to indicate examples of known protease inhibitors.

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No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

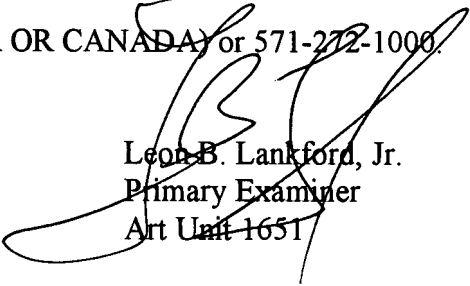
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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